AMENDED IN ASSEMBLY AUGUST 18, 2003

AMENDED IN ASSEMBLY JULY 21, 2003

AMENDED IN ASSEMBLY JUNE 30, 2003

AMENDED IN SENATE JUNE 3, 2003

AMENDED IN SENATE APRIL 30, 2003

AMENDED IN SENATE APRIL 21, 2003

AMENDED IN SENATE APRIL 10, 2003

SENATE BILL No. 857

Introduced by Senator Speier

February 21, 2003

An act to amend Sections ~~14043.15,~~ *14043.1, 14043.15, 14043.65, 14043.75,* 14123.25, and 14172.5 of, to amend the heading of Article 1.3 (commencing with Section 14043) of Chapter 7 of Part 3 of Division 9 of, and to add Sections 14043.26, 14043.27, 14043.28, 14043.29, 14043.341, 14043.47, 14105.05, and 14170.10 to, the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

SB 857, as amended, Speier. Medi-Cal: providers.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services, pursuant to which medical benefits are provided to public assistance recipients and certain other low-income persons.

This bill would revise responsibilities of providers and applicants for participation as providers in the Medi-Cal program.

This bill would also revise the standards that providers are required to meet in maintaining records of benefits provided by them under the Medi-Cal program.

The bill would impose restrictions upon Medi-Cal providers upon the dispensing or furnishing of certain drugs and devices, and for clinical laboratory tests or examinations.

Existing law authorizes the Director of Health Services to prescribe policies, limit health care service payment rates, and adopt rules and regulations in connection with the Medi-Cal program.

This bill would authorize the director, without taking regulatory action, to ~~establish Medi-Cal program reimbursement rates and~~ adopt and annually update designated coding systems.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The heading of Article 1.3 (commencing with Section 14043) of Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code is amended to read:

Article 1.3. Provider Enrollment, Application, and Participation

SEC. 2. *Section 14043.1 of the Welfare and Institutions Code is amended to read:*

14043.1. As used in this article:

(a) ''Abuse'' means either of the following:

(1) Practices that are inconsistent with sound fiscal or business practices and result in unnecessary cost to the federal medicaid and Medicare programs, the Medi-Cal program, another state's medicaid program, or other health care programs operated, or financed in whole or in part, by the federal government or any state or local agency in this state or any other state.

(2) Practices that are inconsistent with sound medical practices and result in reimbursement by the federal medicaid and Medicare programs, the Medi-Cal program or other health care programs operated, or financed in whole or in part, by the federal government or any state or local agency in this state or any other state, for services that are unnecessary or for substandard items or

services that fail to meet professionally recognized standards for health care.

(b) ''Applicant'' means any individual, partnership, group, association, corporation, institution, or entity, and the officers, directors, owners, managing employees, or agents thereof, that applies to the department for enrollment as a provider in the Medi-Cal program.

(c) *"Appropriate volume of business" means a volume that is consistent with the information provided in the application and any supplemental information provided by the applicant or provider, and is of a quality and type that would reasonably be expected based upon the size and type of business operated by the applicant or provider.*

(d) "Business address" means the location where an applicant or provider provides services, goods, supplies, or merchandise, directly or indirectly, to a Medi-Cal beneficiary. A post office box, commercial box, vehicle, or vessel is not a business address.

(e) ''Convicted'' means any of the following:

(1) A judgment of conviction has been entered against an individual or entity by a federal, state, or local court, regardless of whether there is a posttrial motion or an appeal pending or the judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed.

(2) A federal, state, or local court has made a finding of guilt against an individual or entity.

(3) A federal, state, or local court has accepted a plea of guilty or nolo contendere by an individual or entity.

(4) An individual or entity has entered into participation in a first offender, deferred adjudication, or other program or arrangement where judgment of conviction has been withheld.

~~(d)~~

(f) "Debt due and owing" means 60 days have passed since a notice or demand for repayment of an overpayment or other amount resulting from an audit or examination, for a penalty assessment, or for any other amount due the department was sent to the provider, regardless of whether the provider is an institutional provider or a noninstitutional provider and regardless of whether an appeal is pending.

(g) "Enrolled or enrollment in the Medi-Cal program" means authorized under any processes by the department or its agents or

contractors to receive, directly or indirectly, reimbursement for the provision of services, goods, supplies, or merchandise to a Medi-Cal beneficiary.

(h) ''Fraud'' means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or herself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

~~(e)~~

(i) "Location" means a street, city, or rural route address or a site or place within a street, city, or rural route address, and the city, county, state, and nine digit ZIP Code.

(j) "Not currently enrolled at the location for which the application is submitted" means either of the following:

(1) The provider is changing location and moving to a different location than that for which the provider was issued a provider number.

(2) The provider is adding an additional location to that currently used to provide services, goods, supplies, or merchandise to Medi-Cal beneficiaries, and for which the provider was issued a provider number.

(k) "Preenrollment period" includes the period of time during which an application package for enrollment, continued enrollment, or for the addition of or change in a location is pending.

(1) "Professionally recognized standards of health care" means statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue recognize as applying to those peers practicing or providing care within a state.

(2) When the United States Department of Health and Human Services has declared a treatment modality not to be safe and effective, practitioners that employ that treatment modality shall be deemed not to meet professionally recognized standards of health care. This paragraph shall not be construed to mean that all other treatments meet professionally recognized standards of care.

(l) ''Provider'' means any individual, partnership, group, association, corporation, institution, or entity, and the officers, directors, owners, managing employees, or agents of any partnership, group association, corporation, institution, or entity,

that provides services, goods, supplies, or merchandise, directly or indirectly, to a Medi-Cal beneficiary and that has been enrolled in the Medi-Cal program.

~~(f) "Enrolled or enrollment in the Medi-Cal program" means authorized under any and all processes by the department or its agents or contractors to receive, directly or indirectly, reimbursement for the provision of services, goods, supplies, or merchandise to a Medi-Cal beneficiary.~~

~~(g) "Professionally recognized standards of health care" means statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a state. When the United States Department of Health and Human Services has declared a treatment modality not to be safe and effective, practitioners that employ that treatment modality shall be deemed not to meet professionally recognized standards of health care. This definition shall not be construed to mean that all other treatments meet professionally recognized standards of care.~~

~~(h)~~

(m) "Unnecessary or substandard items or services" means those that are either of the following:

(1) Substantially in excess of the provider's usual charges or costs for the items or services.

(2) Furnished, or caused to be furnished, to patients, whether or not covered by Medicare, medicaid, or any of the state health care programs to which the definitions of applicant and provider apply, and which are substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care. The department's determination that the items or services furnished were excessive or of unacceptable quality shall be made on the basis of information, including sanction reports, from the following sources:

(A) The professional review organization for the area served by the individual or entity.

(B) State or local licensing or certification authorities.

(C) Fiscal agents or contractors, or private insurance companies.

(D) State or local professional societies.

(E) Any other sources deemed appropriate by the department.

SEC. 3. Section 14043.15 of the Welfare and Institutions Code is amended to read:

14043.15. (a) The department may adopt regulations for certification of each applicant and each provider in the Medi-Cal program. No certification shall be required for clinics licensed under Section 1204 of the Health and Safety Code, clinics exempt from licensure under Section 1206 of the Health and Safety Code, health facilities licensed under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, or natural persons licensed or certified under Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act.

(b) *(1)* An applicant or provider who is a natural person, and is licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act, or the Chiropractic Initiative Act, or is a professional corporation, as defined in subdivision (b) of Section 13401 of the Corporations Code, *shall comply with Section 14043.26 and* shall be enrolled in the Medi-Cal program ~~only~~ as either an individual provider or as a rendering provider in a provider group *at each location for which an application package has been approved*, notwithstanding that the applicant or provider meets the requirements to qualify as exempt from clinic licensure under subdivision (a) or (m) of Section 1206 of the Health and Safety Code~~, and shall comply with Section 14043.26~~.

(2) A provider enrolled in the Medi-Cal program pursuant to paragraph (1), who has disclosed in the application package that the provider's practice includes the rendering of services solely at one, or at more than one, health facility, as defined in Section 1250 of the Health and Safety Code, shall not be required to enroll at each health facility location and may utilize the provider number granted upon enrollment pursuant to paragraph (1) to claim reimbursement from the Medi-Cal program for services rendered by the provider to Medi-Cal beneficiaries at all of those health facilities.

(c) An applicant or provider licensed as a clinic pursuant to Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code may be enrolled in the Medi-Cal program as a clinic and need not comply with Section 14043.26.

(d) An applicant or provider that meets the requirements to qualify as exempt from clinic licensure under subdivisions (b) to (*l*), inclusive, or subdivisions (n) to (p), inclusive, of Section 1206 of the Health and Safety Code *shall comply with Section 14043.26 and* may be enrolled in the Medi-Cal program as either a clinic or within any other provider category for which the applicant or provider qualifies ~~and shall comply with Section 14043.26~~. An applicant or provider to which any of the clinic licensure exemptions specified in this subdivision apply shall document in its application package the legal and factual ~~justification~~ *basis* for the clinic license exemption claimed.

~~SEC. 3.~~

(e) Notwithstanding subdivisions (a), (b), (c), and (d), an applicant or provider that meets the requirements to qualify as exempt from clinic licensure pursuant to subdivision (h) of Section 1206 of the Health and Safety Code, including an intermittent site that is operated by a licensed primary care clinic and for which the licensed primary care clinic provides all staffing, protocols, equipment, supplies, and billing services, need not enroll in the Medi-Cal program as a separate provider and need not comply with Section 14043.26 if the licensed primary care clinic operating the applicant or provider clinic has notified the department of its separate locations, premises, or intermittent sites.

SEC. 4. Section 14043.26 is added to the Welfare and Institutions Code, to read:

14043.26. (a) (1) On and after January 1, 2004, an applicant that is not currently enrolled in the Medi-Cal program, or a provider applying for continued enrollment, upon written notification from the department that enrollment for continued participation of all providers in a specific provider of service category or subgroup of that category to which the provider belongs will occur, or a provider not currently enrolled at a location where the provider intends to provide services, goods, supplies, or merchandise to a Medi-Cal beneficiary, shall submit a complete application package for enrollment, continuing enrollment, or enrollment at a new location or a change in location. The application package shall consist of a completed and signed application form, signed under penalty of perjury or notarized pursuant to Section 14043.25, a disclosure statement, a provider

agreement, and all attachments or changes to the form, statement, or agreement.

~~(2) For the purposes of this section and Sections 14043.27, 14043.28, and 14043.29, "location" means a street or city address or a site or place within a street and city address, where the applicant or provider provides services, goods, supplies, or merchandise, directly or indirectly, to a Medi-Cal beneficiary.~~

~~(3) For purposes of this section and Sections 14043.27, 14043.28, and 14043.29, "not currently enrolled at the location for which the application is submitted" means either of the following:~~

~~(A) The provider is changing location and moving to a different location than that for which the provider was issued a provider number.~~

~~(B) The provider is adding an additional location to that currently used to provide services, goods, supplies, or merchandise to Medi-Cal beneficiaries, and for which the provider was issued a provider number.~~

~~(4) For purposes of this section, "preenrollment period" includes the period of time during which an application package for enrollment, continued enrollment, or for the addition of or change in a location is pending.~~

~~(5)~~

(2) Clinics licensed by the department pursuant to Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code and certified by the department to participate in the Medi-Cal program shall not be subject to this section.

~~(6)~~

(3) Health facilities licensed by the department pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code and certified by the department to participate in the Medi-Cal program shall not be subject to this section.

~~(7)~~

(4) Adult day health care providers licensed pursuant to Chapter 3.3 (commencing with Section 1570) of Division 2 of the Health and Safety Code and certified by the department to participate in the Medi-Cal program shall not be subject to this section.

~~(8)~~

(5) Home health agencies licensed pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code and certified by the department to participate in the Medi-Cal program shall not be subject to this section.

~~(9)~~

(6) Hospices licensed pursuant to Chapter 8.5 (commencing with Section 1745) of Division 2 of the Health and Safety Code and certified by the department to participate in the Medi-Cal program shall not be subject to this section.

(b) Within 30 days after receiving an application package submitted pursuant to subdivision (a), the department shall provide written notice that the application package has been received and, if applicable, that there is a moratorium on the enrollment of providers in the specific provider of service category or subgroup of the category to which the applicant or provider belongs. This moratorium shall bar further processing of the application package.

(c) *(1) If the applicant package submitted pursuant to subdivision (a) is from an applicant or provider who is a physician who meets the qualifications listed in paragraph (2), the applicant or provider shall be considered a physician preferred provider and shall be granted provisional provider status pursuant to this section and for a period of no more than 18 months, effective from the date on the notice from the department. A physician who desires consideration as a physician preferred provider pursuant to this subdivision shall request consideration from the department by notation on the application package, by cover letter, or by other means identified by the department in a provider bulletin. If a physician who requests consideration as a physician preferred provider does not meet the qualifications listed in paragraph (2), the physician shall be notified by the department within 90 days and the application package submitted shall be processed in accordance with this section.*

(2) To be considered a physician preferred provider, the applicant or provider shall meet all of the following criteria:

(A) Hold a current license as a physician and surgeon issued by the California Medical Board, which license shall not have been revoked, whether stayed or not, suspended, placed on probation, or subject to other limitation.

(B) Be a current faculty member of a teaching hospital or a current preferred provider with a Joint Commission for Accreditation of Healthcare Organizations accredited health plan.

(C) Have full, current, unrevoked, and unsuspended privileges at a Joint Commission for Accreditation of Healthcare Organizations accredited general acute care hospital.

(D) Not have any adverse entries in the Healthcare Integrity and Protection Databank.

(3) The department may recognize other provider categories as qualifying for preferred provider status if criteria similar to those set forth in paragraph (2) are identified for other provider categories. The department shall consult with interested parties and appropriate stakeholders to identify similar criteria for other provider categories so that preferred provider status can be granted to additional applicants and providers.

(d) Within ~~120~~ *180* days after receiving an application package submitted pursuant to subdivision (a) *from an applicant or provider who does not qualify for preferred provider status under subdivision (c),* the department shall give written notice to the applicant or provider that any of the following applies:

(1) The applicant or provider is being granted provisional provider status for a period of 12 months, effective from the date on the notice.

(2) The application package is incomplete. The notice shall identify any additional information or documentation that is needed to complete the application package.

(3) The department is exercising its authority under Section 14043.37, 14043.4, or 14043.7, and is conducting background checks, preenrollment inspections, or unannounced visits.

(4) The application package is denied for any of the following reasons:

(A) Pursuant to Section 14043.2 or 14043.36.

(B) For lack of a license necessary to perform the health care services or to provide the goods, supplies, or merchandise directly or indirectly to a Medi-Cal beneficiary, within the applicable provider of service category or subgroup of that category.

(C) The period of time during which an applicant or provider has been barred from reapplying has not passed.

(D) For other stated reasons authorized by law.

~~(d)~~

(e) (1) If the application package that was noticed as incomplete under subdivision ~~(c)~~ *(d)* is resubmitted with all requested information and documentation, and received by the department within 35 days of the date on the notice, the department shall, within 60 days *of the resubmission,* send a notice that any of the following applies:

(A) The applicant or provider is being granted provisional provider status for a period of 12 months, effective from the date on the ~~approval~~ notice.

(B) The application package is denied for any other reasons provided for in paragraph (4) of subdivision ~~(c)~~ *(d)*.

(C) The department is exercising its authority under Section 14043.37, 14043.4, or 14043.7 to conduct background checks, preenrollment inspections, or unannounced visits.

(2) *(A)* If the application package that was noticed as incomplete under ~~subdivision (c)~~ *paragraph (2) of subdivision (d)* is not resubmitted with all requested information and documentation and received by the department within 35 days of the date on the notice, the application package shall be denied by operation of law. The applicant or provider may reapply by submitting a new application package that shall be reviewed de novo. ~~However, if~~

(B) If the failure to resubmit is by a provider applying for continued enrollment, the failure shall make the provider also subject to ~~temporary suspension and immediate~~ deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program. ~~In addition, where~~

(C) Notwithstanding subparagraph (A), if the notice of an incomplete application package included a request for information or documentation related to grounds for denial under Section 14043.2 or 14043.36, the applicant or provider may not reapply for *enrollment or continued enrollment in the Medi-Cal program or for participation in any health care program administered by the department or its agents or contractors for a period of* three years.

~~(e)~~

(f) (1) If the department exercises its authority under Section 14043.37, 14043.4, or 14043.7 to conduct background checks, preenrollment inspections, or unannounced visits, the applicant or provider shall receive notice, from the department, after the

conclusion of the background check, preenrollment inspections, or unannounced visit of either of the following:

(A) The applicant or provider is granted provisional provider status for a period of 12 months, effective from the date on the notice.

(B) Discrepancies or failure to meet program requirements, as prescribed by the department, have been found to exist during the preenrollment period.

(2) *(A)* The notice shall identify the discrepancies or failures, and whether remediation can be made or not, and if so, the time period within which remediation must be accomplished. Failure to remediate discrepancies and failures as prescribed by the department, or notification that remediation is not available, shall result in denial of the application by operation of law. The applicant or provider may reapply by submitting a new application package that shall be reviewed de novo. ~~However, if~~

(B) If the failure to remediate is by a provider applying for continued enrollment, the failure shall make the provider also subject to ~~temporary suspension and immediate~~ deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program. ~~In addition, where~~

(C) Notwithstanding subparagraph (A), if the discrepancies or failure to meet program requirements, as prescribed by the director, included in the notice were related to grounds for denial under Section 14043.2 or 14043.36, the applicant or provider may not reapply for three years.

~~(f)~~

(g) If provisional provider status is granted pursuant to this section, a separate provider number shall be issued for each location for which an application package has been approved. This separate provider number shall be used exclusively for the location for which it is issued, unless the practice of the provider's profession or delivery of services, goods, supplies, or merchandise is such that ~~it includes the delivery of~~ services, goods, supplies, or merchandise *are rendered or delivered* at locations other than the provider's business address and ~~the~~ *this* practice or delivery of services, goods, supplies, or merchandise has been disclosed in the application package approved by the department when the provisional provider status was granted.

~~(g)~~

(h) An applicant or a provider whose application for enrollment, continued enrollment, or a new location or change in location has been denied pursuant to this section, may appeal the denial in accordance with Section 14043.65.

~~SEC. 4.~~

SEC. 5. Section 14043.27 is added to the Welfare and Institutions Code, to read:

14043.27. (a) If an applicant or provider is granted provisional provider status pursuant to Section 14043.26 and, during the 12-month provisional status period, the department conducts any announced or unannounced visits or any additional inspections or reviews pursuant to this chapter or Chapter 8 (commencing with Section 14200), or the regulations adopted thereunder, *or pursuant to Section 100185.5 of the Health and Safety Code,* and discovers or otherwise determines the existence of any ground to deactivate the provider number or suspend the provider from the Medi-Cal program pursuant to this chapter or Chapter 8 (commencing with Section 14200), or the regulations adopted thereunder, or if any of the circumstances listed in subdivision (c) occur, the department shall terminate the provisional provider status of the provider.

(b) Termination of provisional provider status shall include deactivation of all provider numbers used by the provider at any location to obtain reimbursement from the Medi-Cal program and removal of the provider from enrollment in the Medi-Cal program, except where the termination is based upon a ground related solely to a specific location for which provisional provider status was granted. Termination of provisional provider status based upon grounds related solely to a specific location may include failure to have an established place of business, failure to possess the business or zoning permits or other approvals necessary to operate a business, or failure to possess the appropriate licenses, permits, or certificates necessary for the provider of service category or subcategory identified by the provider in its application package. Where the grounds relate solely to a specific location, the termination of provisional provider status shall include only deactivation of the provider numbers issued for the specific locations that the grounds apply to and shall include removal of the provider from enrollment in the Medi-Cal program only if, after

deactivation of the provider numbers, the provider does not possess any valid provider numbers.

(c) The following circumstances are grounds for termination of provisional provider status:

(1) The provider, persons with an ownership or control interest in the provider, or persons who are directors, officers, or managing employees of the provider have been convicted of any felony, or any misdemeanor involving fraud or abuse in any government program, related to neglect or abuse of a patient in connection with the delivery of a health care item or service, or in connection with the interference with, or obstruction of, any investigation into health care related fraud or abuse, or have been found liable for fraud or abuse in any civil proceeding, or have entered into a settlement in lieu of conviction for fraud or abuse in any government program within 10 years of the date of the application package.

(2) There is a material discrepancy in the information provided to the department, or with the requirements to be enrolled, that is discovered after provisional provider status has been granted and that cannot be corrected because the discrepancy occurred in the past.

(3) The provider has provided material information that was false or misleading at the time it was provided.

(4) The provider failed to have an established place of business ~~for the location~~ *at the business address* for which the application package was submitted at the time of any onsite inspection, announced or unannounced visit, or any additional inspection or review conducted pursuant to this article or a statute or regulation governing the Medi-Cal program, unless the practice of the provider's profession or delivery of services, goods, supplies, or merchandise is such that ~~it includes the delivery of~~ services, goods, supplies, or merchandise *are rendered or delivered* at locations other than the business address and ~~the~~ *this* practice or delivery of services, goods, supplies, or merchandise has been disclosed in the application package approved by the department when the provisional provider status was granted.

(5) The provider meets the definition of a clinic under Section 1200 of the Health and Safety Code, but is not licensed as a clinic pursuant to Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code and fails to meet the

requirements to qualify for at least one exemption pursuant to Section 1206 or 1206.1 of the Health and Safety Code.

(6) The provider performs clinical laboratory tests or examinations, but it or its personnel do not meet CLIA, and the regulations adopted thereunder, and the state clinical laboratory law, do not possess valid CLIA certificates and clinical laboratory registrations or licenses pursuant to Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code, or are not exempt from licensure as a clinical laboratory under Section 1241 of the Business and Professions Code.

(7) The provider fails to possess either of the following:

(A) The appropriate licenses, permits, certificates, or other approvals needed to practice the profession or occupation, or provide the services, goods, supplies, or merchandise the provider identified in the application package approved by the department when the provisional provider status was granted and for the location for which the application was submitted.

(B) The business or zoning permits or other approvals necessary to operate a business at the location identified in its application package approved by the department when the provisional provider status was granted.

(8) The provider, or if the provider is a clinic, group, partnership, corporation, or other association, any officer, director, or shareholder with a 10 percent or greater interest in that organization, commits two or more violations of the federal or state statutes or regulations governing the Medi-Cal program, and the violations demonstrate a pattern or practice of fraud, abuse, or provision of unnecessary or substandard medical services.

(9) The provider commits any violation of a federal or state statute or regulation governing the Medi-Cal program or of a statute or regulation governing the provider's profession or occupation and the violation represents a threat of immediate jeopardy or significant harm to any Medi-Cal beneficiary or to the public welfare.

(10) The provider submits claims for payment that subject a provider to suspension under Section 14043.61.

(11) The provider submits claims for payment for services, goods, supplies, or merchandise rendered at a location other than the location for which the provider number was issued, unless the practice of the provider's profession or delivery of services, goods,

supplies, or merchandise is such that ~~it includes the delivery of~~ services, goods, supplies, or merchandise *are rendered or delivered* at locations other than the business address and ~~the~~ this practice or delivery of services, goods, supplies, or merchandise has been disclosed in the application package approved by the department when the provisional provider status was granted.

(12) The provider has not paid its fine, or has a debt due and owing, including overpayments and penalty assessments, to any federal, state, or local government entity that relates to Medicare, medicaid, Medi-Cal, or any other federal or state health care program, and has not made satisfactory arrangements to fulfill the obligation or otherwise been excused by legal process from fulfilling the obligation.

(d) If, during the 12-month provisional status period, the department conducts any announced or unannounced visits or any additional inspections or reviews pursuant to this chapter or Chapter 8 (commencing with Section 14200), or the regulations adopted thereunder, and commences an investigation for fraud or abuse, or discovers or otherwise determines that the provider is under investigation for fraud or abuse by any other state, local, or federal government law enforcement agency, the provider shall be subject to termination of provisional provider status.

(e) A provider whose provisional provider status has been terminated pursuant to this section~~,~~ may appeal the termination in accordance with Section 14043.65.

(f) Any department-recovered fine or debt due and owing, including overpayments, that are subsequently determined to have been erroneously collected shall be promptly refunded to the provider, together with interest paid in accordance with subdivision (e) of Section 14171 and Section 14172.5.

~~(g) For the purposes of this section, a "debt due and owing" means 60 days has passed since a notice or demand for repayment of an overpayment or other amount resulting from an audit or examination, or for a penalty assessment, or for any other amount due the department, was sent to the provider, regardless of whether the provider is an institutional provider or a noninstitutional provider and regardless of whether an appeal is pending.~~

~~SEC. 5.~~

SEC. 6. Section 14043.28 is added to the Welfare and Institutions Code, to read:

14043.28. (a) (1) If ~~the~~ *an application package is denied under Section 14043.26 or* provisional provider status is terminated ~~or an application package is denied~~ *under Section 14043.27*, the applicant or provider may not reapply for enrollment or continued enrollment in the Medi-Cal program or for participation in any health care program administered by the department or its agents or contractors for a period of three years from the date the application package is denied or the provisional provider status is terminated, or from the date of the final decision following an appeal from that denial or termination, except as *provided otherwise in paragraph (2) of subdivision (e), or paragraph (2) of subdivision (f), of Section 14043.26 and as* set forth in this section.

(2) If the application is denied under ~~subdivision (d)~~ *paragraph (2) of subdivision (e)* of Section 14043.26 because the applicant failed to resubmit an incomplete application package or is denied under ~~subdivision (e)~~ *paragraph (2) of subdivision (f)* of Section 14043.26 because the applicant failed to remediate discrepancies, the applicant may resubmit an application in accordance with ~~subdivision (d) or with subdivision (e), respectively.~~ *paragraph (2) of subdivision (d) or paragraph (2) of subdivision (f), respectively.*

(3) If the denial of the application package *is based upon a conviction for any offense or for any act included in Section 14043.36* or termination of the provisional provider status is based upon a conviction for any offense or for any act included in paragraph (1) of subdivision (c) of Section 14043.27, the applicant or provider may not reapply for enrollment or continued enrollment in the Medi-Cal program or for participation in any health care program administered by the department or its agents or contractors for a period of 10 years from the date the application package is denied or the provisional provider status is terminated or from the date of the final decision following an appeal from that denial or termination.

(4) If the denial of the application package *is based upon a conviction for any offense or for any act included in Section 14043.36* or termination of the provisional provider status is based upon two or more convictions for any offense or for any two acts included in paragraph (1) of subdivision (c) of Section 14043.27, the applicant or provider shall be permanently barred from

enrollment or continued enrollment in the Medi-Cal program or for participation in any health care program administered by the department or its agents or contractors.

(5) The prohibition in paragraph (1) against reapplying for three years shall not apply if the denial of the application or termination of provisional provider status is based upon any of the following:

~~(A) The grounds provided for in subdivision (d) of Section 14043.27, if the investigation is closed without any adverse action being taken.~~

~~(B) The grounds provided for in paragraphs (4), (6), or subparagraph (B) of paragraph (7) of subdivision (c) of Section 14043.27.~~

(A) The grounds provided for in paragraph (4), or subparagraph (B) of paragraph (7), of subdivision (c) of Section 14043.27.

(B) The grounds provided for in subdivision (d) of Section 14043.27, if the investigation is closed without any adverse action being taken.

(b) (1) If ~~the denial of~~ an application package ~~or the termination of~~ *is denied under subparagraph (A), (B), or (D) of paragraph (4) of subdivision (d) of Section 14043.26, or with respect to a provider described in subparagraph (B) of paragraph (2) of subdivision (e), or subparagraph (B) of paragraph (2) of subdivision (f), of Section 14043.26, or* provisional provider status is *terminated* based upon any of the grounds stated in subparagraph (A) of paragraph (7), or paragraphs (1), (2), (3), (5), and (8) to (12), inclusive, of subdivision (c) of Section 14043.27, all existing provider numbers assigned to the applicant or provider shall be deactivated and the applicant or provider shall be removed from enrollment in the Medi-Cal program by operation of law.

(2) If the termination of provisional provider status is based upon the grounds stated in subdivision (d) of Section 14043.27 and the investigation is closed without any adverse action being taken, or is based upon the grounds in subparagraph (B) of paragraph (7) of subdivision (c) of Section 14043.27 and the applicant or provider obtains the appropriate license, permits, or approvals covering the period of provisional provider status, the termination taken pursuant to subdivision (c) of Section 14043.27 shall be rescinded, the previously deactivated provider numbers shall be

reactivated, and the provider shall be reenrolled in the Medi-Cal program, unless there are other grounds for taking these actions.

(c) Claims that are submitted or caused to be submitted by an applicant or provider who has been suspended from the Medi-Cal program for any reason or who has had its provisional provider status terminated or had its application package for enrollment or continued enrollment denied and all provider numbers deactivated may not be paid for services, goods, merchandise, or supplies rendered to Medi-Cal beneficiaries during the period of suspension or termination or after the date all provider numbers are deactivated.

~~SEC. 6.~~

SEC. 7. Section 14043.29 is added to the Welfare and Institutions Code, to read:

14043.29. (a) If, at the end of the period for which provisional provider status was granted *under Section 14043.26*, all of the following conditions are met, the provisional status shall cease and the provider shall be enrolled in the Medi-Cal program without designation as a provisional provider:

(1) The provider has demonstrated an appropriate volume of business.

(2) The provisional provider status has not been terminated.

~~(3) The application package for enrollment or continued enrollment or for a new location or change in location has not been denied.~~

~~(4)~~

(3) The provider continues to meet the standards for enrollment in the Medi-Cal program as set forth in this article and Section 51000 and following of Title 22 of the California Code of Regulations.

~~(b) For the purposes of this section, ''appropriate volume of business" means a volume that is consistent with the information provided in the application and any supplemental information provided by the applicant or provider, and is of a quantity and type that would reasonably be expected based upon the size and type of business operated by the applicant or provider.~~

~~(c)~~

(b) (1) An applicant or a provider who applied for enrollment or continued enrollment in the Medi-Cal program, prior to May 1, 2003, and for whom the application has not been approved or

denied, or who has not received a notice on or before January 1, 2004, that the department is exercising its authority under Section 14043.37, 14043.4, or 14043.7 to conduct background checks, preenrollment inspections, or unannounced visits, shall be granted provisional provider status effective on January 1, 2004. Applications from applicants or providers who have been so noticed prior to January 1, 2004, shall be processed in accordance with subdivision (e) of Section 14043.26.

(2) Applications from applicants or providers that have been received by the department after May 1, 2003, but prior to January 1, 2004, shall be processed in accordance with Section 14043.26, except that these application packages shall be deemed to have been received by the department on January 1, 2004.

~~(d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, clarify, or make specific this section, Section 14043.27, and Section 14043.28 by means of a provider bulletin or similar instruction, without taking further regulatory action. The department shall consult with interested parties and appropriate stakeholders in implementing these sections, including all of the following:~~

~~(1) Notifying provider representatives of the proposed action or change. The notice shall occur at least 10 business days prior to the meeting provided for in paragraph (2).~~

~~(2) Scheduling at least one meeting to discuss the action or change.~~

~~(3) Allowing for written input regarding the action or change.~~

~~(4) Providing at least 30 days' advance notice on the implementation and effective date of the action or change, unless other time periods are required by law.~~

~~SEC. 7.~~

SEC. 8. Section 14043.341 is added to the Welfare and Institutions Code, to read:

14043.341. (a) Each provider that dispenses, as defined in Section 4024 of the Business and Professions Code, or that furnishes, as defined in Section 4026 of the Business and Professions Code, a controlled drug, a dangerous drug, or a dangerous device to a Medi-Cal beneficiary, or a drug or device requiring a written order or prescription for the drug or device to be covered under the Medi-Cal program, or who obtains a

biological specimen from a Medi-Cal beneficiary for the performance of a clinical laboratory test or examination shall maintain a record of the signature of the person receiving the drug or device or from whom a biological specimen was obtained; the printed name of the recipient *or person from whom the biological specimen was obtained*; the date signed; *for a drug or device,* the prescription number or a description of the item or items dispensed *or furnished*; and if the recipient is not the beneficiary for whom the drug or device was ordered or prescribed or from whom a biological specimen was obtained, a notation of the recipient's relationship to that beneficiary. *The signature and printed name of the person from whom a biological specimen is obtained on the requisition provided to the clinical laboratory for performance of the test or examination for which the specimen was obtained shall be sufficient to comply with this section if a copy of the signed requisition is kept by the provider obtaining the biological specimen. Furthermore, no signature is required under this section where the biological specimen is obtained for the purpose of anatomical pathology examinations performed during the inpatient or outpatient surgery if a notation of the performance of the anatomical pathology examination appears in the medical record.*

(b) For purposes of this section:

(1) ''Biological specimen'' shall have the same meaning as in Section 1206 of the Business and Professions Code.

(2) ''Clinical laboratory test or examination'' shall have the same meaning as in Section 1206 of the Business and Professions Code.

(3) ''Controlled substance'' shall mean any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

(4) ''Dangerous drug'' or ''dangerous device'' has the same meaning as in Section 4022 of the Business and Professions Code.

(5) ''Drug or device'' means:

(A) ''Drug,'' as defined in Section 4025 of the Business and Professions Code.

(B) ''Device,'' as defined in Section 4023 of the Business and Professions Code.

(C) Pharmaceuticals, medical equipment, medical supplies, orthotics and prosthetics appliances, and other product-like supplies or equipment.

(c) Nothing in this section shall require a provider who dispenses or furnishes a complimentary sample of a dangerous drug to maintain the signature of the person receiving that drug, provided no charge is made to the patient, and an appropriate record is entered in the patient's chart. ~~Where~~

(d) If the dispensing or furnishing *of a drug or device* occurs on a periodic basis within an established ~~physician-patient~~ *provider-patient* relationship, the signature shall only be required upon the initial dispensing or furnishing of the drug, so long as an appropriate record of each dispensing or furnishing is entered in the patient's chart.

~~(d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of a provider bulletin or similar instruction, without taking further regulatory action. The department shall consult with interested parties and appropriate stakeholders in implementing this section, including all of the following:~~

~~(1) Notifying provider representatives of the proposed action or change. The notice shall occur at least 10 business days prior to the meeting provided for in paragraph (2).~~

~~(2) Scheduling at least one meeting to discuss the action or change.~~

~~(3) Allowing for written input regarding the action or change.~~

~~(4) Providing at least 30 days' advance notice on the implementation and effective date of the action or change, except where another time period is required by law.~~

~~SEC. 8.~~

(e) If the obtaining of a biological specimen is required in order that a test or examination occur on a periodic basis within an established provider-patient relationship, the signature shall only be required upon obtaining the biological specimen necessary for the initial test or examination so long as an appropriate record of each test or examination is entered in the patient's chart.

SEC. 9. Section 14043.47 is added to the Welfare and Institutions Code, to read:

14043.47. (a) A provider doing business as a sole proprietorship, partnership, ~~professional medical corporation, or nursing~~ *or professional* corporation under Part 4 (commencing with Section 13400) of Division 3 of the Corporations Code or a rendering physician provider in a group who utilizes nonphysician medical practitioners to provide services, goods, supplies, or merchandise to Medi-Cal beneficiaries shall develop and maintain a quality review system for health care delivery that meets the specific supervisory requirements applicable to such providers, pursuant to the Business and Professions Code or other state or federal law.

(b) A provider doing business as a sole proprietorship, ~~partnership, professional medical corporation, or nursing~~ *partnership, or professional* corporation under Part 4 (commencing with Section 13400) of Division 3 of the Corporations Code or a rendering physician provider in a group who fails to comply with the requirements of this section is subject to temporary suspension from the Medi-Cal program and deactivation of all provider numbers.

(c) A physician doing business as a sole proprietorship, partnership, or ~~professional medical corporation under the~~ *professional corporation under* Part 4 (commencing with Section 13400) of Division 3 of the Corporations Code or a rendering physician provider in a group~~,~~ may not be enrolled at more than three business addresses unless there is a ratio of at least one physician providing supervision for every three locations.

(d) A physician doing business as a sole proprietorship, partnership, or professional medical corporation under Part 4 (commencing with Section 13400) of Division 3 of the Corporations Code or a rendering physician provider in a group~~,~~ who fails to comply with the requirements of this section is subject to temporary suspension from the Medi-Cal program and deactivation of all of his or her provider numbers.

~~SEC. 9.~~

SEC. 10. Section 14043.65 of the Welfare and Institutions Code is amended to read:

14043.65. (a) Notwithstanding any other provision of law, any applicant whose application for enrollment as a provider or whose certification is denied; or any provider who is denied continued enrollment or certification, *or denied enrollment for a*

new location, who has been temporarily suspended, who has had payments withheld, who has had one or more provider numbers used to obtain reimbursement from the Medi-Cal program deactivated*, or whose provisional status has been terminated* pursuant to this article or Section 14107.11*, or Section 100185.5 of the Health and Safety Code,* or who has had a civil penalty imposed pursuant to *subdivision (a) of* Section 14123.25; or any billing agent, as defined in Section 14040, when the billing agent's registration has been denied pursuant to subdivision (e) of Section 14040.5, may appeal this action by submitting a written appeal, including any supporting evidence, to the director or the director's designee. Where the appeal is of a withholding of payment pursuant to Section 14107.11, the appeal to the director or the director's designee shall be limited to the issue of the reliability of the evidence supporting the withhold and shall not encompass fraud or abuse. The appeal procedure shall not include a formal administrative hearing under the Administrative Procedure Act and shall not result in reactivation of any deactivated provider numbers during appeal. An applicant, provider, or billing agent that files an appeal pursuant to this section shall submit the written appeal along with all pertinent documents and all other relevant evidence to the director or to the director's designee within 60 days of the date of notification of the department's action. The director or the director's designee shall review all of the relevant materials submitted and shall issue a decision within 90 days of the receipt of the appeal. The decision may provide that the action taken should be upheld, continued, or reversed, in whole or in part. The decision of the director or the director's designee shall be final. Any further appeal shall be required to be filed in accordance with Section 1085 of the Code of Civil Procedure.

(b) No applicant whose application for enrollment~~,~~ as a provider~~,~~ has been denied pursuant to Section 14043.2, 14043.36, or 14043.4 may reapply for a period of three years from the date the application is denied. ~~Where~~ *If* the provider has appealed the denial, the three-year period shall commence upon the date of final action by the director or the director's designee.

SEC. 11. Section 14043.75 of the Welfare and Institutions Code is amended to read:

14043.75. *(a)* The director may, in consultation with interested parties, by regulation, adopt, readopt, repeal, or amend

additional measures to prevent or curtail fraud and abuse. Regulations adopted, readopted, repealed, or amended pursuant to this section shall be deemed emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). These emergency regulations shall be deemed necessary for the immediate preservation of the public peace, health and safety, or general welfare. Emergency regulations adopted, amended, or repealed pursuant to this section shall be exempt from review by the Office of Administrative Law. The emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and publication in the California Code of Regulations.

(b) Notwithstanding any other provision of law, the director may, without taking regulatory action pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, implement, interpret, or make specific Sections 14043.26, 14043.27, 14043.28, 14043.29, and 14043.341 by means of a provider bulletin or similar instruction. The department shall notify and consult with interested parties and appropriate stakeholders in implementing, interpreting, or making specific those provisions described in this subdivision, including all of the following:

(1) Notifying provider representatives of the proposed action or change. The notice shall occur at least 10 business days prior to the meeting provided for in paragraph (2), unless the law being implemented, interpreted, or made specific requires a shorter time period.

(2) Scheduling at least one meeting with interested parties and appropriate stakeholders to discuss the action or change.

(3) Allowing for written input regarding the action or change.

(4) Providing at least 30 days advance notice of the effective date of the action or change, unless the law requiring the interpretation or specificity requires a shorter time period.

SEC. 12. Section 14105.05 is added to the Welfare and Institutions Code, to read:

14105.05. (a) Notwithstanding Section 14105, and any other provision of law, the director may, without taking regulatory action pursuant to Chapter 3.5 (commencing with Section 11340)

of Part 1 of Division 3 of Title 2 of the Government Code~~, take one or both of the following actions:~~

~~(1) Establish the reimbursement rates identified in this chapter, including rates for payment for services not rendered under a contract pursuant to Chapter 8 (commencing with Section 14200).~~

~~(2) Adopt~~ *adopt* and annually update the federal Healthcare Common Procedure Coding System codes (formerly known as the United States Healthcare Common Procedure Coding System HCPCS) or any other coding system required for compliance with this chapter, federal medicaid requirements, or the federal Health Insurance Portability and Accountability Act (HIPAA).

(b) The director may take the actions described in subdivision (a) by means of publication in the California Regulatory Notice Register, the Medi-Cal Provider Manual, or similar publications.

(c) The publication of ~~reimbursement rates or~~ coding systems pursuant to subdivision (a) shall include an effective date for the published ~~rates or~~ coding systems.

(d) Nothing in this section shall be construed to affect the department's compliance with federal medicaid law or regulations relating to the adoption of Medi-Cal reimbursement rates.

~~SEC. 10.~~

SEC. 13. Section 14123.25 of the Welfare and Institutions Code is amended to read:

14123.25. (a) In lieu of, or in addition to, the imposition of any other sanction available to it, including the sanctions and penalties authorized under Section 14123.2 or 14171.6, and as the ''single state agency'' for California vested with authority to administer the Medi-Cal program, the department shall exercise the authority granted to it in Section 1002.2 of Title 42 of the Code of Federal Regulations, and may also impose the mandatory and permissive exclusions identified in Section 1128 of the federal Social Security Act (42 U.S.C. Sec. 1320a-7), and its implementing regulations, and impose civil penalties identified in Section 1128A of the federal Social Security Act (42 U.S.C. Sec. 1320a-7a), and its implementing regulations, against applicants and providers, as defined in Section 14043.1 or against billing agents, as defined in Section 14040.1. The department may also terminate, or refuse to enter into, a provider agreement authorized under Section 14043.2 with an applicant or provider, as defined in Section 14043.1, upon the grounds specified in Section 1866(b)(2)

of the federal Social Security Act (42 U.S.C. Sec. 1395cc(b)(2). Notwithstanding Section 100171 of the Health and Safety Code or any other provision of law, any appeal by an applicant, provider, or billing agent of the imposition of a civil penalty, exclusion, or other sanction pursuant to this subdivision shall be in accordance with Section 14043.65, except that where the action is based upon conviction for any crime involving fraud or abuse of the Medi-Cal, medicaid, or Medicare programs, or exclusion by the federal government from the medicaid or Medicare programs the action shall be automatic and not subject to appeal or hearing.

(b) In addition, the department may impose the intermediate sanctions identified in Section 1846 of the Social Security Act (42 U.S.C. Sec. 1395w-2), and its implementing regulations, against any provider that is a clinical laboratory, as defined in Section 1206 of the Business and Professions Code. The imposition and appeal of this intermediate sanction shall be in accordance with Article 8 (commencing with Section 1065) of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations.

(c) (1) In addition, the department may issue a written warning notice of improper billing or improper cost report computation to a provider via certified mail, return receipt requested whenever a review of the provider's paid claims or a provider's cost report demonstrate a pattern of improper billing or improper cost report computation. The review shall not take into account claims that were denied or reduced before being paid. The warning notice shall be in a format that specifically apprises the provider of the item or service improperly billed, and if applicable, the deficiencies in the manner in which provider costs were computed. The warning notice may be issued with annual cost report audit findings, or in addition to any audit or any other action that the department is authorized to take. The failure of the department to exercise its discretion to issue the warning notice shall not be interpreted and shall not limit its authority to audit or take any action authorized by law. The warning notice shall provide the provider with the opportunity to contest the warning notice and explain to the department the correctness of the provider's bill or cost report computation. If the department accepts the provider's explanation, in whole or in part, no further action related to the notice or part of the notice that the department accepts as correct shall be taken pursuant to this section.

(2) Civil money penalties may be imposed in the following circumstances:

(A) If a provider presents or causes to be presented claims for payment by the Medi-Cal program that are:

(i) Billed improperly, and are for a service or item about which the provider has received two or more warning notices of improper billing, the provider may, in addition to any other penalties that may be prescribed by law, be subject to a civil money penalty of one hundred dollars ($100) per claim, or up to two times the amount improperly claimed for each item or service, whichever is greater.

(ii) For a service or item for which the department solicits provider costs for use in calculating Medi-Cal reimbursement or in calculating and assigning Medi-Cal reimbursement rates, the cost reports relevant to the claims are improperly calculated, and the provider has received two or more warning notices of improper cost report computation regarding substantially similar errors, the provider may, in addition to any other penalties that may be prescribed by law, be subject to a civil money penalty of one hundred dollars ($100) per adjustment by the department to the costs submitted by the provider, or up to two times the amount improperly claimed for each item or service, whichever is greater.

(B) If a provider presents or causes to be presented claims for payment by the Medi-Cal program that are:

(i) Billed improperly, and are for a service or item about which the provider has received three or more warning notices of improper billing, or has been assessed a penalty under subparagraph (A), the provider may, in addition to any other penalties that may be prescribed by law, be subject to a civil money penalty of one thousand dollars ($1,000) per claim, or up to three times the amount improperly claimed for each item or service, whichever is greater.

(ii) For a service or item for which the department solicits provider costs for use in calculating Medi-Cal reimbursement or in calculating and assigning Medi-Cal reimbursement rates, and the cost reports relevant to the claims are improperly calculated, and the provider has received three or more warning notices of improper cost report computation regarding substantially similar errors, or has been assessed a penalty under subparagraph (A), the provider may, in addition to any other penalties that may be

prescribed by law, be subject to a civil money penalty of one thousand dollars ($1,000) per adjustment by the department to the costs submitted by the provider, or three times the amount claimed for each item or service, whichever is greater.

(3) Any provider subjected to civil money penalties under paragraph (2) may appeal the decision to assess penalties pursuant to Section 100171 of the Health and Safety Code.

~~SEC. 11.~~

SEC. 14. Section 14170.10 is added to the Welfare and Institutions Code, to read:

14170.10. (a) No provider shall submit a claim to the department or its fiscal intermediaries for the dispensing or furnishing of a controlled drug, a dangerous drug, or a dangerous device, or a drug or device requiring a written order or prescription for the drug or device to be covered under the Medi-Cal program or for the performance of a clinical laboratory test or examination, unless the provider's records contain an order authorized by Section 4019 of the Business and Professions Code, or a prescription, including an electronic transmission prescription, signed by the person lawfully authorized by his or her practice act to prescribe or order the dispensing or furnishing of that drug or device to, or for the performance of a clinical laboratory test or examination that meets the federal CLIA standard for test requisition as set forth in Section ~~493.1105~~ *493.1241* of Title 42 of the Code of Federal Regulations upon, a Medi-Cal beneficiary, except the following:

(1) Providers who are physicians, clinics, hospitals, or other nonpharmacists and who are legally authorized to dispense or furnish drugs or devices directly to their patients, may in lieu of the requirements of this subdivision include a notation in their patients' medical charts reflecting they have dispensed or furnished the drug or device directly to the patient as authorized by the Business and Professions Code.

(2) Anatomical pathology examinations may be ordered by physicians by notation within the patients medical record during inpatient or outpatient surgery provided that these examinations comply with federal CLIA requirements. Any claims made contrary to this section shall be subject to recovery as overpayments.

(b) For purposes of this section:

(1) ‘‘Signed’’ shall include a signature that meets the conditions of the Electronic Signature in Global and National Commerce Act (15 U.S.C. Sec. 7001).

(2) ‘‘Controlled substance’’ shall mean any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

(3) ‘‘Dangerous drug’’ or ‘‘dangerous device’’ has the same meaning as in Section 4022 of the Business and Professions Code.

(4) ‘‘Drug or device’’ means:

(A) ‘‘Drug,’’ as defined in Section 4025 of the Business and Professions Code.

(B) ‘‘Device,’’ as defined in Section 4023 of the Business and Professions Code.

(C) Pharmaceuticals, medical equipment, medical supplies, orthotics and prosthetics appliances, and other product-like supplies or equipment.

(5) ‘‘Prescription’’ has the same meaning as in Section 4040 of the Business and Professions Code.

(6) ‘‘Electronic transmission prescription’’ includes both image and data prescriptions.

(7) ‘‘Electronic image transmission prescription’’ means any prescription order for which a facsimile of the order is received by a pharmacy or other appropriate provider from a licensed prescriber and that is reduced to writing and processed by the pharmacy or other appropriate provider in accordance with applicable provisions of the Business and Professions Code, including Section 4070.

(8) ‘‘Electronic data transmission prescription’’ means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy or other appropriate provider and which is reduced to writing and processed by the pharmacy or other appropriate provider in accordance with applicable provisions of the Business and Professions Code, including Section 4070. The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(9) ‘‘Clinical laboratory test or examination’’ means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of

obtaining scientific data that may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

(c) Notwithstanding *any other provision of law, the director may, without taking regulatory action pursuant to* Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, ~~the department may implement this section by means of a provider bulletin or similar instruction, without taking further regulatory action. The department shall consult with interested parties and~~ *implement, interpret, or make specific this section by means of a provider bulletin or similar instruction. The department shall notify and consult with interested parties and* appropriate stakeholders in implementing*, interpreting, or making specific* the provisions of this section, including all of the following:

(1) Notifying provider representatives of the proposed action or change. The notice shall occur at least 10 business days prior to the meeting provided for in paragraph (2)*, unless the law being implemented, interpreted, or made specific requires a shorter time period*.

(2) Scheduling at least one meeting *with interested parties and appropriate stakeholders* to discuss the action or change.

(3) Allowing for written input regarding the action or change.

(4) Providing at least 30 days' advance notice on the ~~implementation and effective date of the action or change.~~ *effective date of the action or change, unless the law requiring the interpretation or specificity requires a shorter time period.*

~~SEC. 12.~~ *SEC. 15.* Section 14172.5 of the Welfare and Institutions Code is amended to read:

14172.5. (a) No later than 60 days after the completion of an audit or examination pursuant to Sections 10722 and 14170, the department shall issue the first statement of account status or demand for repayment.

(b) (1) Notwithstanding the provisions of Section 14172 or any other law, when it is established that an overpayment has been made to ~~an~~ *a* provider or a civil money penalty assessed pursuant

to Section 14123.2, 14123.25, 14171.5, or 14171.6 is due from a provider, the department shall not begin liquidation of the overpayment until 60 days after issuance of the first statement of accountability or demand for repayment after issuance of the audit or examination report establishing the overpayment or the document establishing the penalty. The department shall pursue liquidation of the overpayment or penalty upon expiration of the 60-day period. If the department finds, upon appeal, that no overpayment was made to, or no penalty is due from, the provider, the department shall repay the amount collected, together with the payment of interest thereon, from the date occurring 60 days after issuance of the first statement of accountability or demand for repayment after issuance of the audit or examination report alleging the overpayment or the document establishing *the* penalty.

(2) This subdivision shall not be construed so as to affect the department's authority under other provisions of law for liquidation of overpayments to providers.

(c) Liquidation of the overpayment or penalty may be by any of the following:

(1) Lump-sum payment by the provider.

(2) Offset against current payments due to the provider.

(3) A repayment agreement executed between the provider and the department.

(4) Any other method of recovery available to and deemed appropriate by the director.

(d) An offset against current payments shall continue until one of the following occurs:

(1) The overpayment or penalty is recovered.

(2) The department enters into an agreement with the provider for repayment of the overpayment or penalty.

(3) The department determines, upon appeal, that there is no overpayment or that the penalty should not have been assessed.

(e) The provider shall pay interest on any unrecovered overpayments or penalty assessments as provided by subdivision (h) of Section 14171. If recovery of a disallowed payment has been made by the department, a provider who prevails in an appeal of a disallowed payment or penalty assessment shall be paid interest as provided by subdivision (g) of Section 14171.

(f) Nothing in this section shall prohibit a provider from repaying all or a part of the disputed overpayment or penalty assessment without prejudice to the provider's right to a hearing pursuant to subdivision (b) of Section 14171 or pursuant to Section 100171 of the Health and Safety Code.

(g) If a provider appeals the assessment of a civil money penalty, liquidation of the penalty shall be deferred until the appeal is rejected or a final administrative decision is issued.

(h) If on the basis of reliable evidence, the department has a valid basis for believing that, with respect to a provider, proceedings have been or will shortly be instituted in a state or federal court for purposes of determining whether the provider is insolvent or bankrupt under appropriate state or federal law, or that a provider is or will shortly be taking action which reasonably might seriously hinder or defeat the department's ability to collect overpayments in the future, the department may immediately adjust any payments to the provider to a level necessary to insure that no overpayment to the provider is made.

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